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Mr. Jeffrey Nast, Sr. Asst. Regional Counsel
US EPA Region III
1650 Arch Street
Philadelphia, PA 19103

RE: GSK Counterproposal to U.S. EPA ("Agency") Potential RCRA Violations

Dear Mr. Nast:

Thank you for taking the time to meet with us on January 23, 2014. As discussed during the Settlement Conference, GSK hereby submits the following counterproposal to the Agency's Opportunity to Show Cause Letter ("Letter").

In response to the Letter, GSK respectfully request reconsideration of the RCRA penalties assessed in accordance with the Agency's RCRA Civil Penalty policy based upon Section 3008 of RCRA, 42 U.S.C. §6928. Specifically, we ask that the Agency reconsider the penalties assessed for multiple violations resulting from a single transgression, as well as its calculation of the gravity component of such penalties.

Multiple Violations Resulting from a Single Transgression

With respect to Counts 1 through 4, it is GSK's assertion that the majority of the penalties are associated with a single transgression (a failure to determine the organic concentration of hazardous waste in a 150 gallon tank used to hold waste ethanol). It is our understanding that if a threshold determination had been conducted that indicated the waste had over 10 ppmw VOCs, the tank and certain associated equipment in contact with hazardous waste containing at least 10% organic material would be subject to 40 CFR 265 Subpart BB, and if over 500 ppmw, the tank would be subject to 40 CFR Subpart CC. While GSK does not dispute the fact that Subpart BB was triggered by our failure to conduct a proper waste evaluation, additional penalties were assessed for the same transgression in Counts 2 (failure to monitor equipment with at least 10% VOCs), 3 (failure to mark that equipment), and 4 (failure to determine maximum organic vapor pressure and failure to comply with fixed roof requirements). Further, Count 1 indicates that

failure to comply with the above (or other) requirements for hazardous waste generators results in loss of the 90-day generator permit exemption, triggering another penalty for the same transgression.

It is GSK's position that the claims associated with Count 1 appear to be inconsistent with the Agency's Policy which states, in relevant part, that "[a] separate penalty should be proposed in an administrative proceeding and obtained in settlement or litigation for each separate violation that results from an independent act (or failure to act) by the violator and is substantially distinguishable from any other claim in the complaint for which a penalty is to be assessed. A given claim is independent of, and substantially distinguishable from, any other claim when it requires an element of proof not needed by the others."

Based on the Letter, it appears that the penalties assessed in Count 1 are triggered by the same transgression that forms the basis for the penalties assessed in each of Counts 2 through 4. There is no separate element of proof associated with Count 1 aside from those addressed in Counts 2 through 4. The application of Count 1 as an additional layer of noncompliance for otherwise cited violations appears to be tenuous. The statutory citations used to justify this Count (Section 3005(a) and (e) of RCRA) require the Agency to establish hazardous waste permit and interim status programs, and the regulatory citation Count 1 designates as implementing this requirement (40 CFR 270.1(b)) exempts from permitting generators who accumulate hazardous waste on-site for less than the time periods provided in 40 C.F.R. §262.34. The Agency has not asserted that GSK exceeded the 90-day time period provided in 40 C.F.R. §262.34.

Notwithstanding any violations and based on GSK's interpretation of this Claim noted above, GSK believes this Count 1 should either be eliminated or the penalty reduced to minor/minor given that the penalties assessed in Count 1 are based upon a single transgression and have been assessed in Counts 2 through 4 and the fact that GSK would not otherwise be required to obtain a permit for the accumulation of hazardous waste on site.

Gravity Based Component of the Penalties

The Agency's RCRA Civil Penalty Policy indicates that penalties are assessed based on a matrix that takes into consideration the potential for harm and the extent of deviation from the regulatory requirement. Each is assigned as being major, moderate, or minor. Based upon information provided during the Settlement Conference, it is our understanding that the penalties assessed in Counts 1, 2, and 4 in the Letter were classified as "moderate/moderate" and Count 3 as "moderate/major".

With respect to Counts 2 through 4, the primary constituent of the associated hazardous waste was ethanol, which was stored in a 150 gallon tank. All of the waste ethanol was properly disposed of as hazardous waste. Ethanol has a relatively low degree of toxicity to human health and has negligible impact on the environment. It is an ingredient in many food and beverage products. According to the National Library of Medicine's ChemIDplus database, its LD 50

(7,060 mg/kg) indicates that it is non-hazardous when administered orally, and its LC 50 (20,000 ppm) would result in an OSHA classification as a minor hazard. Further, ethanol has a very low degree of aquatic toxicity (LC 50 11,200 mg/l), it photodegrades quickly (10 hour half life), breaks down quickly in soil, and it has a negligible global warming potential. Based on these properties, it is GSK's opinion that only a minor potential for harm would be anticipated when the waste was managed in its 150 gallon tank system.

Based on the above, GSK respectfully request that the penalties associated with Counts 2 through 4 be reclassified as minor/minor.

Proposed Equitable Penalty Calculation

Count 1: Minor/Minor \$430 (or, as proposed above, remove count) ✓

Count 2: Minor/Minor

Gravity: \$150

Multi-day: $\$150 \times 179 = 26,850$

Count 3: \$0 (due to multiple transgression policy) ✓

Count 4: Minor/Minor

Gravity: \$150

Multi-day: $\$150 \times 179 = 26,850$

No proposed changes to EPA's recommendations for Counts 5 – 8

Count 5: \$9,120

Count 6: \$1,000

Count 7: \$1,000

Count 8: \$1,000

Subtotal: \$66,250

Reduction for avoiding legal expenses (20%): -\$13,250

Total: \$53,000

GSK welcomes the Agency's response to this counterproposal, and we look forward to an amicable resolution. GSK is committed to being a responsible corporate citizen and complying with applicable regulations. GSK considers the environmental regulations as minimum standards and we will continue to work with the Agency to make GSK a global leader in environmental performance.

Each of the cited Counts has been resolved and we are taking steps to ensure that they do not reoccur.

Thank you in advance your consideration. Please do not hesitate to contact me if you have any questions or require any further information.

Sincerely,

Deanna R. Herman

Deanna R. Herman
Environment Manager

cc: Robert Nash, GSK
Samantha Wilson, GSK